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Erik Andersen

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EXAMINER

CARPENTER, WILLIAM R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,827	Applicant(s) ANDERSEN ET AL.	
	Examiner WILLIAM CARPENTER	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 May 2009 has been entered.

Claim Objections

2. Claim 9 is objected to because of the following informalities: Applicant recites "A closure according to claim 1, **wherein the connector**, one of said face and end surface" [formatting altered for emphasis]. However, this does not appear to be a grammatically correct sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

Art Unit: 3767

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding Claim 1, Applicant recites the limitation "...such that when a tubular member extends through the passage slit the tubular member will not stretch or deform the closure member". However, express support for this limitation in Applicant's detailed disclosure as originally filed could not be found. Paragraph 6 of Applicant's detailed disclosure recites "[b]y providing a slit as explained above, the risk of improper alignment of the catheter or stent system and the closure is reduced thereby also the risk of the catheter or stent system stretching/deforming the closure to such an extent in the area of the slit that a gap is created between the outer wall of the catheter or stent system and the closure". Furthermore, Paragraph 10 recites "[i]n a preferred embodiment, the closure member is made from a resilient material which is adapted to deform in the area of the protrusion/indentation when the face of the resilient closure and the end surface of the main section are biased towards each other". There is nothing to suggest that the disclosed and claimed closure member is configured such that it will not deform when a tubular member is passed through the slit. Appropriate correction is required. Additionally, Claim 1 recites the limitation "the walls of the tapered core section do not contact the walls of the longitudinal passage of the connector when the closure member is not engaged by the tubular member". However, express support for this limitation in Applicant's detailed disclosure as originally filed could not be found. This limitation appears to be based on the supplied figures, however these figures are not in sufficient detail as to clearly demonstrate that no portion of the

Art Unit: 3767

tapered core section contacts the walls of the longitudinal passageway prior to insertion of the tubular member. Appropriate correction is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 9, 10, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, Applicant recites the limitation “the passage slit having a **larger extent at the second surface than the first surface** such that the **smaller extend of the passage slit is positioned in the concave portion at the second surface** and a **larger extent of the passage slit is associated with the tapered core section on the first surface**” [formatting altered for emphasis]. It is not clear how the device could simultaneously have a “larger extent at the second surface than the first surface” and the smaller extent being associated with the concave portion of the second surface and the larger extent being associated with the tapered core section of the first section. These two qualities of the passage slit appear to be mutually exclusive from one another. Appropriate correction is required.

Regarding Claim 9, Applicant recites the limitation “one of said face and end surface”. However, this limitation renders the claim indefinite as no “face” has been previously introduced, nor is immediate clear two what “end surface” Applicant refers. Appropriate correction is required.

Art Unit: 3767

Regarding Claim 10, Claim 10 is listed as “Previously Presented”. However, this claim depends from Claim 8 which is listed by Applicant as being “Cancelled”. As such, it is not clear what limitation(s) are required by Claim 10. Appropriate correction is required.

Regarding Claim 16, Applicant recites the limitation “**the passage slit having a larger extent at the first surface than the second surface** such that the **smaller extent of the passage slit is positioned in the tapered core section at the first surface** and **a larger extent of the passage is associated with the concave portion**” [formatting altered for emphasis]. However, this limitation renders the claims indefinite as it is not clear how the device might simultaneously have a larger and smaller extent at the first surface as compared to the second surface. These two qualities of the passage slit appear to be mutually exclusive from one another. Appropriate correction is required. Additionally, Claim 16 recites a limitation drawn towards a “catheter”. However, no such catheter is previously introduced within the body of the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3767

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-5 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,199,948 ("McPhee") in view of US Patent No. 5,149,327 ("Oshiyama").

Regarding Claims 1-4, 11, and 16, MCPhee discloses a closure (15) for a valve of a connector of a haemostatic valve (Fig. 1). MCPhee discloses the connector to comprise a longitudinally extending main section (13) having a longitudinally extending, through going passage (21) with a valve at a proximal end of the connector (11). MCPhee discloses the closure to comprise a closure member (15) made from a resilient material (Col. 3, Ln. 31-32) having first and second opposite end surfaces (Fig. 2). MCPhee discloses the first surface to comprise a tapered core section (27 and 31) which extends into a longitudinal passage of the connector (Fig. 1). MCPhee discloses the second surface comprises a concave portion (35) which is adapted to be engaged by a tubular member which is configured to extend through the closure member (Fig. 5). MCPhee discloses that the tapered core section of the first surface is tapered along the entire length of the tapered core section which is positioned in the longitudinal passage of the connector, such that its diameter is larger at the proximal extent as compared to

Art Unit: 3767

the distal extent (Fig. 2). In the instant case the phrase "tapered" is afforded its broadest reasonable interpretation as "to become smaller or thinner towards one end" or "to become progressive smaller towards one end". As can be clearly seen with respect to the tapered core section (27 and 31) of the device of McPhee the entire portion is shown becoming smaller and thinner, particularly as compared to the enlarged portion (29). However, should this argument not be found persuasive, Examiner submits that the tapered core section could refer solely to the section (31). McPhee discloses that the longitudinal passage includes ribs (25) which prevent contact between the walls of the longitudinal passage (24) from contacting the walls of the tapered core section (Fig. 3) when the closure member is not engaged by the tubular member. Alternatively, should the tapered core section be interpreted to comprise only the section (31), as is clearly seen in Figure 1 the tapered walls of the core section do not contact the walls of the longitudinal passage. McPhee discloses the device to include a passage slit (33) being normally closed and extending between the two end surfaces. McPhee discloses that the passage slit is arranged to open by the tubular member which is configured to extend therethrough (Fig. 5).

McPhee fails to explicitly disclose that the passage slit has a larger extent at the first surface as compared to the extent at the second surface. However, Oshiyama discloses a closure (10A) for a valve of a connector of a hemostatic valve assembly (20). Oshiyama discloses the closure to comprise a second surface (11) and a first surface (12) and having a passage slit (13A and 14A in combination), the passage slit being normally closed and arranged by the tubular member inserted therethrough.

Art Unit: 3767

Oshiyama discloses that the passage is configured such that the smaller extent (15A and 17A) is positioned on the second surface and the larger extent (16A and 18A) is associated with the first surface (Fig. 2). Oshiyama discloses that instead of a single slit, a plurality of passage slits (13A and 14A). Oshiyama discloses that these slits intersect to form a first, common point of contact on the first surface and extend radially outwardly from the point of contact at the first surface (Figure 2). Similarly the slits define a second, common point of contact on the second surface.

While Oshiyama does disclose the egress of the slit to be larger than the ingress, Oshiyama fails to explicitly disclose that the ingress should be at most $1/10^{\text{th}}$ the length of the egress. However, as Applicant has failed to explicitly disclose that this particular ratio solves any expressly stated problem or is anything more than one of the numerous configurations for the passage slit one having ordinary skill in the art at the time the invention was made would have found obvious to use, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the ingress to be at most $1/10^{\text{th}}$ the length of the egress, since it has been held that determining the workable or optimum range of a result effective variable requires only routine and customary skill in the art.

Oshiyama discloses that the closure member may be used by inserting a tubular member from the ingress of the second face (11) through the egress of the first face (12) whereby the structure of the passage slit will inherently serve as a guide to force the tubular member into a particular angular alignment with respect to the closure member (Col. 7, Ln. 43-49). Oshiyama discloses that such an insertion from the second

Art Unit: 3767

face to the first face allows even a thick tubular member to be easily inserted therethrough (Col. 4, Ln. 16-20). It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the passage slit of the device of McPhee to have a smaller extent at the second surface ingress and a larger extend at the first surface egress, as disclosed by Oshiyama, in order to allow easy insertion of thicker tubular members without placing excessive stress and strain on the valve.

While neither McPhee nor Oshiyama disclose that the passage slit is formed such that the closure member will not stretch or deform under insertion of the closure member, Examiner submits that the stretching and deformation is as much a product of the tubular member as it is the structure of the closure member. It is inherent that there exists a tubular member having a sufficiently small diameter such that the closure member does not deform upon its insertion into the passage slit. Furthermore, it is noted that the closure member of the modified invention of McPhee possesses the same claimed tapering of the seal and passage slit and would be expected to behave in a similar manner as Applicant's invention.

Regarding Claim 5, McPhee discloses that the first end surface and at least a portion of the second end surface (35a) define two substantially parallel planes (Fig. 1), and wherein an axis extending between the first and second common point of contact, as modified in view of Oshiyama, is substantially perpendicular to the two planes.

Regarding Claim 12, McPhee discloses the valve with the closure to be arranged near a proximal end of the connector (Fig. 1).

Regarding Claim 13, McPhee discloses that the second surface of the closure member is oriented to face the proximal end of the connector (Fig. 1).

Regarding Claims 14 and 15, while McPhee does disclose that in one embodiment of the invention the connector may include a side arm (75), McPhee fails to disclose that the side arm should be provided with side arm tubing having a stop cock for connection thereto. However, Oshiyama discloses a hemostatic assembly (50) having a connector (20) and a resilient closure member (23). Oshiyama discloses the connector to have a side arm (27) including side arm tubing (51) connected thereto and terminating in a stopcock (52) at the opposite end. Oshiyama discloses that such a configuration may be used to introduce liquid medicaments or collect blood. It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the connector of the device of McPhee having a side arm and associated side arm tubing and stopcock, as disclosed by Oshiyama, in order to allow the infusion of fluid medicaments or the sampling of blood.

10. Claims 9 and 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,199,948 ("McPhee") and US Patent No. 5,149,327 ("Oshiyama") as applied to Claim 1 above, and further in view of US Patent No. 5,114,408 ("Fleischhaker").

Regarding Claims 9 and 10, McPhee discloses that a face (generally the first surface) of the closure abuts a proximal end surface (37) of the main section of the connector. However, McPhee fails to disclose that one of the face and the end surface should be provided with an integral protrusion corresponding to an indentation provided

Art Unit: 3767

in the other of the face and the end surface. However, Fleischhaker discloses a similar hemostatic assembly (Fig. 1) comprising a connector (1) and a closure member (6).

Fleischhaker discloses that a face of the closure member abuts the proximal end surface of the connector. To secure this abutment Fleischhaker discloses providing the proximal end face of the connector with integral protrusions/ribs (16) that correspond to indentations on the face of the abutting closure member, thereby forming a liquid tight periphery, holding the closure member in place. While in the instant case Fleischhaker discloses the protrusions to be integral with the connector, not the closure member, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the protrusions to be integral with the closure member, corresponding to receiving openings on the connector, since it has been held that the mere reversal of the essential working parts of an invention requires only routine and customary skill in the art. Fleischhaker discloses that the closure member is formed of a resilient material which is adapted to deform in the area of the protrusion and the indentation so as to provide a liquid tight seal about the outer periphery at a passage at the proximal end of the connector (Fig. 1). Such interference fit relationships are well-known in the art of fluid handling devices, whereby the interference and deformation results in an improved fluid seal. As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to provide the proximal end surface of the closure member and the face of the closure member of the device of McPhee with a indentation and protrusion, as disclosed by Fleischhaker, as to permit the resilient closure member to deform about the area of the protrusion and the indentation when the face and end

Art Unit: 3767

surface are biased towards each other in order to provide a liquid tight seal about the outer periphery of the longitudinal passage at a proximal end thereof.

Response to Arguments

11. Applicant's arguments filed 14 May 2009 have been fully considered but they are not persuasive.

Applicant argues that the cited references fail to disclose the claimed passage slit having a larger extent at the first surface as compared to the first surface such that the closure member will not stretch or deform when a tubular member is inserted therethrough. However, this is not found to be persuasive. The invention of Oshiyama discloses a closure member having passage slit with a larger egress than ingress, such that the larger extent of the closure member is associated with the first surface and the smaller extent of the closure member is associated with the second surface. Oshiyama discloses that such a configuration improves the manner in which larger tubular members may be inserted, whereby the egress opens up more easily. While Oshiyama fails to explicitly disclose that the passage slit is such that a tubular member inserted therethrough will not stretch or deform the closure member, this relationship is held to generally be alluded to by Oshiyama disclosure of increasing the ease with which larger, thicker members may be inserted through. Furthermore, it is held that there inherently exists a tubular member that may be inserted through the seal such that no deformation of the closure member occurs. Additionally, it is held that Applicant's original disclosure does not possess support for such a claimed relationship and in fact

Art Unit: 3767

the closure member of Applicant's invention does indeed deform due to the presence of a tubular member inserted into the passage slit (see Fig. 4).

Applicant argues that the cited references fail to disclose a closure member that is tapered along the entire length of the tapered core section which is positioned in the longitudinal passage of the connector. However, this is not found to be persuasive. As discussed above, in the instant case the phrase "tapered" is afforded its broadest reasonable interpretation as "to become smaller or thinner towards one end" or "to become progressive smaller towards one end". As can be clearly seen with respect to the tapered core section (27 and 31) of the device of McPhee the entire portion is shown becoming smaller and thinner, particularly as compared to the enlarged portion (29). However, should this argument not be found persuasive, Examiner submits that the tapered core section could refer solely to the section (31).

Applicant argues that McPhee's disclosure of ribs teaches away from the limitation that the walls of the tapered core section do not contact the walls of the longitudinal passage when the closure member is not engaged by the tubular member. In the instant case it is held that the ribs do not constitute the walls of the longitudinal passage. As can be seen in Fig. 3 of the McPhee reference the walls of the tapered core section do not contact the walls of the longitudinal passage, only the ribs. Furthermore, Examiner submits that the surface (31) may be considered the tapered core section, in which case the device is illustrated such that not even the ribs contact this surface (Fig. 1). Finally, it is not immediately clear if Applicant's originally filed disclosure even possesses the support for such a limitation.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the reversal of the components [the indentation and the projection] of the components of Fleishchhaker is not merely a matter of design choice, but changes the operability and effectiveness of the disclosed valve design. However, this is not found to be persuasive. It has been held that the mere reversal of the essential working parts of an invention requires only routine and customary skill in the art. As such, such a modification would have been obvious to try with respect to the invention of Fleishchhaker, particularly as the reversal of the indentation and the projection will still result in a valid securement mechanism. Furthermore, Fleishchhaker does indeed disclose the closure member to comprise a face that is biased towards the proximal end surface connector, particularly by use of the cap means (2) which is held to compress the closure member and the connector, deforming the closure member and creating a fluid tight seal about the periphery.

Applicant argues that there is no teaching, suggestion, or motivation to combine the teachings of McPhee, Oshiyama, and Fleishchhaker. However, this is not found to be persuasive. Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

Art Unit: 3767

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine can be found within the references themselves. In the instant case it would have been obvious to replace the generic slit of McPhee with one of the type of Oshiyama to improve the insertion of larger diameter tubular bodies therethrough. The motivation to combine the teachings of Fleischhaker and McPhee resides in the benefits or more securely disposing the closure member within the connector to prevent movement therebetween improving the fluid tight seal.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/

Examiner, Art Unit 3767

07/07/2009

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767